Initial Approval Date: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Psoriatic Arthritis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Abatacept (Orencia®)
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)
Apremilast (Otezla®)
Certolizumab (Cimzia®)
Etanercept (Enbrel®, Erelzi™, Eticovo®)
Golimumab (Simponi®, Simponi Aria®)
Infliximab (Remicade®, Reflexis™, Inflectra®, Ixifi™)
Ixekizumab (Taltz™)
Secukinumab (Cosentyx™)
Tofacitinib (Xeljanz®, Xeljanz XR®)
Ustekinumab (Stelara™)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a dermatologist or rheumatologist.[2]
- Patient must have had an adequate trial (at least 90 consecutive days within the past 120 days) of or contraindication to methotrexate. If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[2,3,7,14,18,19,20,21]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of ONE of the following criteria:
    - Number of swollen joints
    - Number of tender joints
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Psoriatic Arthritis (PsA)Agents.[3-21]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-12 and -23 Inhibitors			
Ustekinumab (Stelara™)	PsA	≥ 18 years	45 mg initially SC at weeks 0 and 4, followed by 45 mg every 12 weeks thereafter. Coexistent moderate to severe plaque psoriasis and weight more than 100 kg: 90 mg SC initially and 4 weeks later, and then 90 mg every 12 weeks thereafter.
Interleukin-17a Inhibitors			
Secukinumab (Cosentyx™)	PsA	≥ 18 years	With loading dose: 150 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then, 150 mg every 4 weeks.

			Without loading dose: 150 mg SC every 4 weeks. Coexistent moderate to severe plaque psoriasis: 300 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then, 300 mg every 4 weeks; some patients may only require 150 mg/dose.
Ixekizumab (Taltz™)	PsA	≥ 18 years	160 mg administered SC at week 0, followed by 80 mg every 4 weeks.
Janus Associated Kinase Inhibitors			
Tofacitinib (Xeljanz®)	PsA	≥ 18 years	5 mg orally twice daily.
Tofacitinib (Xeljanz XR®)	PsA	≥ 18 years	11 mg orally once daily.
Phosphodiesterase-4 Enzyme Inhibitor			
Apremilast (Otezla®)	PsA	≥ 18 years	30 mg orally twice daily.
Selective T-Cell Costimulation Blockers			
Abatacept (Orencia®)	PsA	≥ 18 years	SC: 125 mg once weekly. IV: at 0, 2 and 4 weeks, then every 4 weeks thereafter < 60 kg: 500 mg 60-100 kg: 750 mg > 100 kg: 1,000 mg
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)	PsA	≥ 18 years	40 mg SC every other week.
Certolizumab (Cimzia®)	PsA	≥ 18 years	400 mg initially SC at week 0, 2, and 4 followed by 200 mg every other week or 400 mg every 4 weeks.
Etanercept (Enbrel®, Erelzi™, Eticovo®)	PsA	≥ 18 years	50 mg SC once weekly.
Golimumab (Simponi®)	PsA	≥ 18 years	50 mg initially SC at week 0, followed by 100 mg at week 2 and then 100 mg every 4 weeks.
Golimumab (Simponi Aria®)	PsA	≥ 18 years	2 mg/kg IV at 0 and 4 weeks, then every 8 weeks.
Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™)	PsA	≥ 18 years	5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Prescriber must provide at least ONE of the following response measure(s):
  - ≥ 20% reduction in tender joint count compared to baseline
  - ≥ 20% reduction in swollen joint count compared to baseline
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of PsA

Conventional Psoriatic Arthritis Therapy	
Generic Name	**Brand Name**
Cyclosporine	Gengraf®, Neoral®
Leflunomide	Arava®
Methotrexate	Trexall®, Rheumatrex®, Otrexup®, Rasuvo®
Sulfasalazine	Azulfidine®

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan® (rituximab)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

Notes:

Ixekizumab (Taltz™)	For psoriatic arthritis patients with coexisting moderate to severe plaque psoriasis, use the dosing regimen for plaque psoriasis.

References:

1. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology,71*(1), 5-32. doi:10.1002/art.40726. Available at https://onlinelibrary.wiley.com/doi/full/10.1002/acr.23789. Accessed on 6/20/19.
2. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2016; 75:499-510. Available at https://ard.bmj.com/content/75/3/499.full. Accessed on 6/20/19.
3. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; March 2019.
4. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2018.
5. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
6. Cyltezo (adalimumab) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.
7. Otezla (apremilast) [prescribing information]. Summit, NJ: Celgene Corporation; June 2017.
8. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April 2019.
9. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corp; May 2018.
10. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; January 2018.
11. Eticovo (etanercept) [prescribing information]. Denmark: Samsung Bioepis; April 2019.
12. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2018.
13. Simponi Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; May 2018.
14. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; June 2018.
15. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; September 2018.
16. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; March 2019.
17. Ixifi (infliximab-qbtx) [prescribing information]. Ringaskiddy, Co. Cork, Ireland: Pfizer Ireland Pharmaceuticals; December 2017.
18. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2018.
19. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2018.
20. Xeljanz/Xeljanz XR (tofacitinib) [prescribing information]. New York, NY: Pfizer; October 2018.
21. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; June 2018.

**Hyrimoz package insert not yet available.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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